



21 Ways to Beat Zimmer



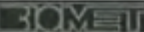
The TRUTH About Zimmer...

*A Webcast Expose!*


Welcome Biomet  
East Coast Distributors  
& Sales Associates!




21 Ways to Beat Zimmer



Biomet Hip Marketing & Engineering Group




Photograph of Hip Group



21 Ways to Beat Zimmer

Biomet's **Strengths** in Hip Reconstruction

Biomet sells a hip stem every 9 minutes...  
That's just in the USA




1. Widest Breadth/Scope Product Offering
2. Longest Clinical History
3. Lower-Risk Technologies
4. Strong Pipeline (ArCom XL, Magnum, ReCap, Medallion, Porous Metal Shells, Diamond-on-Diamond, Ceramic-on-Ceramic)
5. Favorable Market Dynamics
6. Solid, Untarnished Reputation
7. Fast-Growing Salesforce
8. Management Longevity & Industry Commitment
9. DTC Initiatives & Patient Communications

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Biomet's **Weaknesses** in Hip Reconstruction

Biomet has reported lower than expected hip growth




1. Surgeons want "sizzle," we have more "steak"
2. Traditional, measured approach to new product releases
3. Delayed ceramic-on-ceramic introduction
4. Surgeons are more willing to experiment vs. relying on "tried and true"
5. Late to the DTC game

21 Ways to Beat Zimmer

Zimmer remains ORTHOPEDIC ENEMY #1


Following are 21 ways you can help your surgeons:

- **Identify** Zimmer marketing propaganda
- **Clearly See** how Biomet hips are superior
- **Make Critical Evaluations** about what's best for the patient
- **Question** why Zimmer deserves their business in the first place



21 Ways to Beat Zimmer

Biomet's Focus For This Business Year...



1. **Long Term Clinical Success**  
Forged Ti, bi-planar taper w/Porous Plasma Spray.
2. **Metal-on-Metal**  
M2a 28, 32, 38mm...Magnum™ System.
3. **Freedom® Constrained Liner**  
36mm Tri-mode stability.
4. **ArCom® XL**  
Wear is no longer the issue.


Derek Edgar

Exhibit 34  
VF 12-12-18


21 Ways to Beat Zimmer  
#1

**BIOMET**

Zimmer has been dodging our best efforts for **long enough**



**Channel 4**  
**LIVE**  
**NewsChannel 4**




21 Ways to Beat Zimmer  
#1

Extremely **Limited** Clinical Follow-up

**"Nothing kills a good story like clinical results."**


-- Austin Moore



21 Ways to Beat Zimmer  
#1

Extremely **Limited** Clinical Follow-up


In business for 75 years, and Zimmer maintains only **ONE** currently marketed stem with 10-year published follow-up.



Anatomic™ Stem

(The Anatomic™ Stem)

Reference: Zimmer.com, August 27, 2006




21 Ways to Beat Zimmer  
#1

Extremely **Limited** Clinical Follow-up


- Zweymuller Alloclassic Stem  
(4 Papers at 10 yr avg).<sup>3,4,5,6</sup>
- Spotorno CLS Stem  
(3 Papers at 10 year avg).<sup>7,8,9</sup>

...Yet these products were **BOUGHT** and their results are mostly European.

Reference: PubMed Search, August 10, 2006. 8 Stem EIT. Search terms: "Zweymuller," "Zweymuller," "Spotorno," "Spotorno Hip," "Zweymuller."




Zweymuller®



21 Ways to Beat Zimmer  
#2


**Zimmer's Versys® Hip Has No Clinical Support**

- The VerSys® Cementless Hip was studied...in a "Virtual Implantation."
- In this surgical "simulation," the Versys® was shown to "outperform" Zimmer's own Anatomic™ Hip, but only for proximal fixation.
- We are not aware of any published clinical results on the VerSys® Stem.



Zimmer Versys

Reference: Asanuma S, et al. Comparison of the 01 and 02 between the Anatomic Hip fixation component and the Versys Hip cement component using virtual implantation on the ORTHO-VIC workstation. J Orthop Sci. 2003;8(2):332-40.




21 Ways to Beat Zimmer  
#2

**Zimmer's Versys® Hip Has No Clinical Support**


- 11% revision rate @ 3-4 years with the Versys® Cemented Plus (aseptic loosening).

– Author does not advocate use of PMMA pre-coated components for THA.



Zimmer Versys® Cemented

Reference: Einar (AAOS Annual Meeting 2002)






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#3

### Zimmer's Technological "Innovations" Are Hit-or-Miss

- Zimmer Harris Precoat
- 9.5% failure at 8.4 years
- "The mechanisms of failure of the Precoat prostheses included bone-cement loosening, focal osteolysis, stem fracture, and prosthesis-cement debonding."

Reference: Ong, et al. Early failure of precoated femoral components in primary total hip arthroplasty. J Bone Joint Surg Am. 2002 May;84-A(5):799-82.


Colapinto J.J. "Precoat Components: Another Look." Orthopedics, vol. 18, No. 5, pp. 884, September 1995.




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#3

### Zimmer's Technological "Innovations" Are Hit-or-Miss

- Zimmer Poly II




Reference: "Analysis of Surface Damage in retrieved Carbon Fiber Reinforced and Plain Polyethylene." Wright T, Ferrac C, et al., J.B.J.S. (Am) Oct. 1999, 1998.



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#3

### Zimmer's Technological "Innovations" Are Hit-or-Miss

- Harris-Galante Cups
- Good design, overall good reported results, but consistent failures of the locking mechanism.




HG Cup

Reference: Nelson, C, et al. Locking mechanism failure in the Harris-Galante porous acetabular component associated with reversed hip dislocation. J Arthroplasty. 2002 Jun;17(3):507-15.

Wang L, et al. Polyethylene liner dislocation in Harris-Galante acetabular components: a report of 7 cases. J Arthroplasty. 2002 Dec;17(3):70-81.

Grothman, C, et al. Evaluation of polyethylene liner in uncemented Harris-Galante II acetabulum: Report of 8 cases. J Arthroplasty. 2004 Aug;19(5):661-5.


Neumann D, Dorn H. Polyethylene liner dislocation in Harris-Galante acetabular components. Z Orthop Ihre Grenzgeb. 2003 Mar-Apr;137(2):190-4. [Article in German]



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#3

### HG Femoral Component Results


- Harris-Galante Stems
- Matt will give me text...



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
### Biomet's Long-Term (10yr+) Follow-up

- 5 Papers on the **Taperloc®**
- 4 Papers on the **Mallory-Head®**
- 1 Paper on the **Bi-Metric®**
- 1 Paper on the **Integral®**




Simply Launching New Products Does NOT Constitute Innovation!

Reference: Biomet Manufacturing, Inc. "Clinical performance of hip and knee components." July, 2004.




21 Ways to Beat Zimmer  
#4

### Zimmer Offers No Product Heritage


 Bristol-Myers Squibb Company

- Zimmer Hips in 1995
  1. Multilock®
  2. Anatomic™
  3. Anatomic™ HA
  4. Centralign
  5. Harris™
  6. Macrofit™
  7. Option
  8. ZCH™
  9. Austin-Moore™



Switch-1


Reference: Colapinto, Software News, 2005.




**21 Ways to Beat Zimmer**  
**#4**

**Zimmer Offers No Product Heritage**

- **Zimmer Hips in 2004**
  - 1. Multilock®
  - 2. **Anatomic™**
  - 3. Anatomic™ HA
  - 4. Centralign™
  - 5. Harric™
  - 6. Macrofit™
  - 7. Option™
  - 8. ZCH™
  - 9. Austin-Moore™

  
Anatomic




Reference: Zimmer.com, August 25, 2004

**21 Ways to Beat Zimmer**  
**#4**

**Zimmer Offers No Product Heritage**

- **Biomet Hips in 1995**
  - 1. Mallory-Head® (1986)
  - 2. Ranawat/Burstein®
  - 3. Taperloc® (1984)
  - 4. BiMetric® (1984)
  - 5. Integral® (1988)
  - 6. Impact® (1990)





Reference: Biomet, Inc.

**21 Ways to Beat Zimmer**  
**#4**

**Zimmer Offers No Product Heritage**

- **Biomet Hips in 2004**
  - 1. Mallory-Head® -- 16 years
  - 2. Ranawat/Burstein®
  - 3. Taperloc® -- 20 years
  - 4. BiMetric® -- 20 years
  - 5. Integral® -- 16 years
  - 6. Impact® -- 15 years






Reference: Biomet, Inc.

**21 Ways to Beat Zimmer**  
**#5**

**Zimmer Has Big Stories, But Little Support at 10+ Years**

- 1. AML
- 2. Anatomic
- 3. Bi-Metric®
- 4. CLS
- 5. Integral®
- 6. Mallory/Head®
- 7. ~~DISCONTINUED~~
- 8. ~~DISCONTINUED~~
- 9. Taperloc®
- 10. TriLock (old CoCr design)
- 11. Zweymuller/Alloclassic

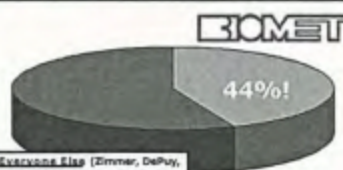


Reference: Biomet Manufacturing, Inc. "Clinical performance of hip and knee components." July, 2004.


**21 Ways to Beat Zimmer**  
**#5**

**Zimmer Has Big Stories, But Little Support at 10+ Years**

- **44%** of ALL currently marketed cementless hip stems with 10yr+ results are Biomet.

  
**BIOMET**  
44%!

Excludes Elap (Zimmer, DePuy, Howmedica, Smith-Nephew, etc.)




Reference: Biomet Manufacturing, Inc. "Clinical performance of hip and knee components." July, 2004.


**21 Ways to Beat Zimmer**  
**#5**

**Zimmer Has Big Stories, But Little Support at 10+ Years**

**15% Growth for FY05**

  
DePuy, Stryker, Zimmer, S-N, Other, **BIOMET**

**13%!**




Reference: Orthopaedic Research News, Vol. 21, No. 3, July, 2004.



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**#5**

**Zimmer Has Big Stories, But Little Support at 10+ Years**

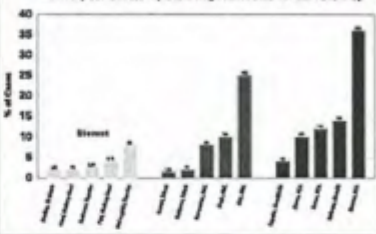
- No company can enjoy meaningful clinical results by revamping entire product lines every 7 to 10 years!
- Clinical Results Do Matter**
  - Hospital Cost Containment
  - Legal Defensibility
  - Patient** Defensibility
  - Credibility & Reputation
  - Selling Confidence




21 Ways to Beat Zimmer  
**#5**

**A CLINICAL PERFORMANCE COMPARISON OF HIP AND KNEE COMPONENTS**

Primary Cementless Hip Stem/Thigh Pain Rates: 10-Year Follow-Up





Y-BEM-176



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**#6**

**Zimmer Has No Design Philosophy**




All things to all surgeons?

21 Ways to Beat Zimmer  
**#6**

**Zimmer Has No Design Philosophy**




- Zimmer Versys® Full Coat
  - Cobalt Chrome
  - Sintered Bead Coating
  - Distally Offloading
  - Collared
  - Bullet Tip

21 Ways to Beat Zimmer  
**#6**

**Zimmer Has No Design Philosophy**

- Zimmer Versys® Fiber Metal Taper
  - Titanium
  - Proximal Fiber Mesh Coating
  - Grit Blast Finish Distally
  - Tapered Geometry
  - Small Size Range 10-18mm

Mallory-Head® Primary Hip




21 Ways to Beat Zimmer  
**#6**

**Zimmer Has No Design Philosophy**

Zimmer Versys® Fiber Metal Taper

- Mulliken BD, Bourne RB, Korachek CH, et al. A tapered titanium femoral stem inserted without cement in a total hip arthroplasty. *J Bone Joint Surg.* 1996;78-A(8):1214-1225. [MALLORY-HEAD® HIP](#)
- Mallory TH. Total hip replacement in the 1990s: the procedure, the patient, the surgeon. *Contemporary Orthopaedics.* 1992;15:427-430. [MALLORY-HEAD® HIP](#)
- Mallory TH, Head WC. A total hip replacement system: clinical experience and recommendations. *Contemporary Orthopaedics.* 1988;17(4):21-28. [MALLORY-HEAD® HIP](#)
- Mozack W, Gardiner R, Harn S, et al. Taperless femoral components. *J Arthroplasty.* 1994;9(5):489-493. [TAPERLOC® HIP](#)




Source: Zimmer.com, August 27, 2004.

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#6

**Zimmer Has No Design Philosophy**




- Zimmer Versys® Beaded Midcoat
  - Cobalt Chrome
  - Sintered Bead Coating (Proximal)
  - Distal Splines

21 Ways to Beat Zimmer  
#6

**Zimmer Has No Design Philosophy**




- Zimmer M/L Taper®
  - Titanium
  - Plasma Spray
  - Flat Tapered Wedge Geometry
  - 510(k) Predicate device: Taperloc®

21 Ways to Beat Zimmer  
#6

**Zimmer Has No Design Philosophy**

- Zimmer Zweymuller® Alloclassic
  - Titanium
  - Grit Blast
  - Tapered Flat Wedge



21 Ways to Beat Zimmer  
#6

**Zimmer Has No Design Philosophy**

- Zimmer Natural® Hip
  - Titanium
  - CSTi with Hydroxyapatite Coating
  - Tapered Geometry

Source: Helms AA, Feige ME, Kasser W, Yang CC, Comargo MP. Cementless primary total hip arthroplasty with a tapered, proximally porous-coated titanium prosthesis: >> a 4- to 8-year retrospective review <<



J Arthroplasty 1999 Oct;15(7):833-4

21 Ways to Beat Zimmer  
#6

**Zimmer Has No Design Philosophy**

- Zimmer has 7 DIFFERENT Hip Systems... of which **no two systems** share a common philosophy.
- VerSys® System
  - Different philosophies within the same family.
  - Cobalt Chrome?
  - Titanium?
  - Sintered Beads?
  - Wire Mesh?
  - Tapered?
  - Cylindrical?
  - Splined?





21 Ways to Beat Zimmer  
#6

**Zimmer Has No Design Philosophy**

- Biomet maintains a consistent, definable, defendable design philosophy in hip engineering and design rationales.
  - Forged Ti
  - Circumferential PPS™
  - Bi-Planar taper

Biomet's founders defected from Zimmer back in 1977 in order to make **BETTER PRODUCTS**






21 Ways to Beat Zimmer  
#7

Not All "Plasma Sprays" Are Created Equal

- Zimmer's Plasma Spray Looks like the Biomet PPS
- It Feels like the Biomet PPS
- It is applied using a similar process to Biomet PPS

But, It is NOT Biomet's PPS.


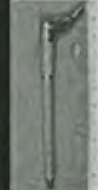

- Very difficult process to replicate  
Pore size...pore distribution...surface Ra...mechanical interlock...bead blast levels...flame duration...operator proficiency...etc.




21 Ways to Beat Zimmer  
#7

Not All "Plasma Sprays" Are Created Equal

- This explanted ZMR® was examined by a researcher, who concluded that INADEQUATE grit blast was the causative factor in this delamination.


Reference: Spelsberg, J. "Daughters and Patients: Effect Analysis of ZMR Zimmer ZMR Hip Stem." Biomet, Inc. Internal Memo, July 2003.



21 Ways to Beat Zimmer  
#7

Not All "Plasma Sprays" Are Created Equal


- No records or reports exist of Biomet's PPS™ surface coating delaminating from the underlying substrate *in vivo* or even under extreme loads.




21 Ways to Beat Zimmer  
#7

Not All "Plasma Sprays" Are Created Equal

- Don't forget that THE PLASMA SPRAY SHOWN ON THE ZMR® IS THE SAME PLASMA SPRAY coating found on the new M/L Taper® Hip.



Zimmer's M/L Taper® Hip System




21 Ways to Beat Zimmer  
#7

Not All "Plasma Sprays" Are Created Equal

In the words of Dr. Roger Emerson:

"[Biomet's] circumferential plasma spray coating appears to provide an effective seal of the femoral canal, preventing debris containing joint fluid from gaining access to the endosteal bone surface. The importance of this observation is that prevention of femoral osteolysis can be expected to prolong the longevity of these circumferentially coated stems."

Roger W. Emerson, M.D., et al. Effect of Circumferential Plasma Spray Porous Coating on the Rate of Progress of Osteolysis after Total Hip Arthroplasty. JBJS 81: 1270-4 (1999)




21 Ways to Beat Zimmer  
#7

Not All "Plasma Sprays" Are Created Equal


Zimmer has no experience and no clinical results with plasma spray.

Biomet has decades of clinical experience with industry-leading results showing the lowest rates of osteolysis and the highest rates of survivorship.



Biomet's Porous Plasma Spray ("PPS") process


Reference: Biomet Manufacturing, Inc. "Clinical performance of Hip and Knee components." July 2004.



21 Ways to Beat Zimmer  
**#7**

Not All "Plasma Sprays" Are Created Equal


Focus On  
**FIXATION**  
Patent Plasma Spray  
& Offset-<sup>TM</sup> 200



Y-BMT-777

21 Ways to Beat Zimmer  
**#8**

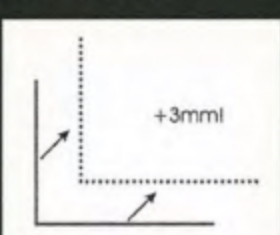
Zimmer's M/L Taper®  
Compromises a Proven Design



21 Ways to Beat Zimmer  
**#8**

Zimmer's M/L Taper®  
Compromises a Proven Design


- M/L Taper Offset is +3mm!



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Zimmer's M/L Taper®  
Compromises a Proven Design

- Excessive offset may irritate greater trochanteric bone and Abductor muscles, leading to painful bouts of bursitis.




Bursitis

21 Ways to Beat Zimmer  
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Zimmer's M/L Taper®  
Compromises a Proven Design

ROM may be compromised if -3.5mm or other "minus" heads must be used to counteract the inherently significant lateral offset found in the M/L Taper.

Biomet provides an 18mm neck length range vs. Zimmer's 14mm.

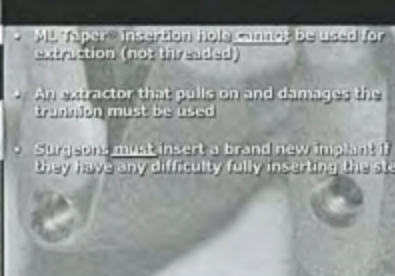


21 Ways to Beat Zimmer  
**#8**

Zimmer's M/L Taper®  
Compromises a Proven Design

- M/L taper® insertion hole ~~cannot~~ be used for extraction (not threaded)
- An extractor that pulls on and damages the transition must be used
- Surgeons must insert a brand new implant if they have any difficulty fully inserting the stem.

Angry Hospital CPO








21 Ways to Beat Zimmer  
**#8**

Zimmer's M/L Taper®  
**Compromises a Proven Design**

50 Rheumatoids at 5yr minimum:  
**100% survivorship**




Biomat Taperloc



21 Ways to Beat Zimmer  
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Zimmer's M/L Taper®  
**Compromises a Proven Design**

92 Octogenarians at 5 yr average:  
**100% survivorship**




Biomat Taperloc



21 Ways to Beat Zimmer  
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Zimmer's M/L Taper®  
**Compromises a Proven Design**

100 Young Patients (37 yrs) at  
8-13yrs: 98% survivorship




Biomat Taperloc

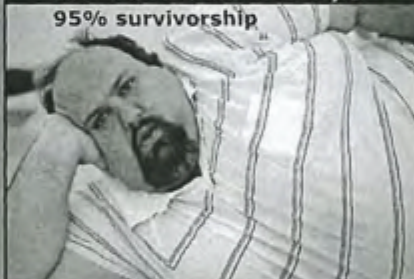

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Zimmer's M/L Taper®  
**Compromises a Proven Design**

140 Obese Patients at 10-18yrs:  
**95% survivorship**




Biomat Taperloc



21 Ways to Beat Zimmer  
**#8**

Zimmer's M/L Taper®  
**Compromises a Proven Design**

4,750 "Traditional" Patients at 10 years:  
**99.6% survivorship**




Biomat Taperloc


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**#8**

Zimmer's M/L Taper®  
**Compromises a Proven Design**

"Zimmer's products should  
not be labeled or marketed  
in ways that may confuse  
them with those of its  
competitors."




- Code of Business Conduct of  
Zimmer Holdings Inc.



21 Ways to Beat Zimmer  
#8

Slide to summarize the taperloc

Paper 1  
Paper 2  
etc





21 Ways to Beat Zimmer  
#9

Zimmer Is Suddenly Committed to Metal-on-Metal (We Think...)


- Centerpulse's Metasul® metal-on-metal system already enjoys a prominent position on Zimmer's website.

Metasul® System

21 Ways to Beat Zimmer  
#9


**Elliot v. Elliot**  
January 30, 2003



Ray Elliot, CEO,  
Zimmer Holdings


"I am not a Metal-on-Metal fan."

Reference: "Zimmer, Inc. Earnings Conference Call", Qtr 4 2002; Jan 30, 2003.



21 Ways to Beat Zimmer  
#9


**Elliot v. Elliot**  
April 27, 2004



Ray Elliot, CEO,  
Zimmer Holdings


"We think Metal-on-Metal is very strong...so we're very excited about Metal-on-Metal."

Reference: "Zimmer, Inc. Earnings Conference Call", Qtr 1 2004; April 27, 2004



21 Ways to Beat Zimmer  
#9


**Elliot v. Elliot**  
January 30, 2003



Ray Elliot, CEO,  
Zimmer Holdings


"We have done so much looking at [metal-on-metal], and concluded that's not where we want to be."

Reference: "Zimmer, Inc. Earnings Conference Call", Qtr 4 2002; Jan 30, 2003.



21 Ways to Beat Zimmer  
#9


**Elliot v. Elliot**  
April 27, 2004



Ray Elliot, CEO,  
Zimmer Holdings

"We don't think [metal-on-metal is] a second place product at all."

Reference: "Zimmer, Inc. Earnings Conference Call", Qtr 1 2004; April 27, 2004





21 Ways to Beat Zimmer  
#9

Zimmer Is Suddenly Committed to Metal-on-Metal (We Think...)

"[Metal ions are] a theoretical concern that is most commonly used as a commercial argument against Metasul by companies that do not have the product."

"There is no identified increased risk of cancer with a metal-on-metal articulation that was used in the past, nor has there been any identified with Metasul..."

John "Elephant Man" Harris.  
("The Elephant Man")

Reference: Zimmer.com, August 27, 2004.

21 Ways to Beat Zimmer  
#9

Remember:

Metal Ions - A Scientific Review

Introduction

M... (text partially obscured)

Y-BEM-175

(You are a friggin' idiot if you haven't given this to every one of your surgeons already.)

21 Ways to Beat Zimmer  
#9

16 Ways to Sell Metal-on-Metal

#1: CoCr alloy has been used for more than 60 years in millions of patients.<sup>1</sup>

#2: Metal ions are a byproduct of virtually every metallic implant, and will be present in the body regardless of the bearing surface chosen.<sup>2-4</sup>

#3: Ceramic-on-ceramic and metal-on-polyethylene total hip replacements can release small amounts of metal ions to the body.<sup>5,6</sup>

#4: The amount of metal ions released from a metal-on-metal implant is extremely low as it is measured on a parts-per-billion level.<sup>7</sup>

#5: The difference between the ion release of a metal-on-metal implant and a metal-on-polyethylene hip may be as little as one to two parts-per-billion.<sup>8,9</sup>

#6: Small amounts of cobalt and chromium appear to be well tolerated by body as evidenced in multiple clinical studies conducted over the 40-year history of metal-on-metal implants, as well as in studies conducted outside of orthopedics.<sup>10-12</sup>

#7: Chromium is an essential micronutrient with a recommended daily requirement of 50 to 200 micrograms per day as established by the FDA.<sup>13</sup>

#8: As with many elements, chromium exists in several atomic valence states. Chromium VI (hexavalent) and chromium III (trivalent) are the two most common. Large doses of hexavalent chromium can be toxic, but toxicity has been established from trivalent chromium.<sup>14-16</sup>

21 Ways to Beat Zimmer  
#9

16 Ways to Sell Metal-on-Metal

#10: The US National Toxicology Program does not list cobalt as a recognized animal or human carcinogen.<sup>17</sup>

#11: Cobalt is an essential element necessary for the formation of vitamin B12, and the metabolism of proteins.<sup>18</sup>

#12: Metal ions are capable of being excreted through the urine. There is a correlation between release into the body (activity) and excretion, which may avoid a local response as well as any toxic build-up on a systemic level.<sup>19-21</sup>

#13: There are no published studies linking carcinogenicity with metal-on-metal implants and metal ion release in the 40-year history of metal-on-metal use. There is no published scientific evidence to suggest a causal relationship between metal-on-metal implants and carcinogenicity on any level.<sup>22-24</sup>

#14: Literature analysis and clinical observations by Vines, Truett, and others support the safe use of metal-on-metal implants and find no link to cancer.<sup>25-27</sup>

#15: Failed metal-on-metal hips can show inflammation of the periprosthetic tissues when there is excessive metal debris.<sup>28</sup> Similar responses have been noted with failed ceramic-on-ceramic and polyethylene hips, or any time the periprosthetic lymph system is unable to keep up with the volume of wear particulate produced by an artificial implant.<sup>29</sup>

#16: Revised metal-on-metal implants have demonstrated a less severe local tissue response compared to metal-on-polyethylene hips.<sup>30</sup>

21 Ways to Beat Zimmer  
#9

Zimmer Is Suddenly Committed to Metal-on-Metal (We Think...)

• Metasul® liners are made from conventional poly.

• Metal inserts are **heat-pressed** into the conventional poly.

• Metal inserts have been reported to **disassociate** from the poly (reference)

21 Ways to Beat Zimmer  
#9

Zimmer Is Suddenly Committed to Metal-on-Metal (We Think...)

• Exposed metal edge has been associated with stem notching and **metallosis**.

• The liners **DO NOT** provide anywhere near the 154 degrees ROM of the M2a-38™.


115 Degrees ROM

21 Ways to Beat Zimmer  
#9

**M2a-38**  
metal-on-metal

**More room to grow  
M2a™ System!**

- Shift to metal-on-metal articulations continues to be very strong.
- In latest quarter, 36% of articulations were metal-on-metal!
- 42-45% metal-metal is possible!

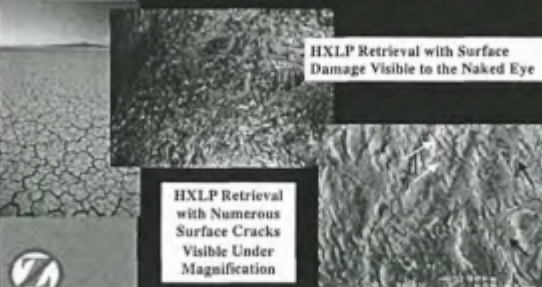


21 Ways to Beat Zimmer  
#10


**Zimmer's HXLP Longevity® and Durasul® Polys Are Showing Weaknesses**

HXLP Retrieval with Surface Damage Visible to the Naked Eye

HXLP Retrieval with Numerous Surface Cracks Visible Under Magnification



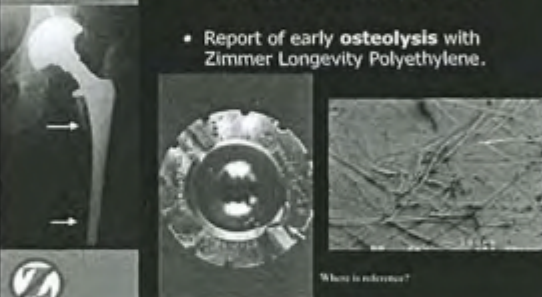
Reference: Buckland et al. JBJS June 2004




21 Ways to Beat Zimmer  
#10

**Zimmer's HXLP Longevity® and Durasul® Polys Are Showing Weaknesses**

- Report of early **osteolysis** with Zimmer Longevity Polyethylene.



Where is reference?





21 Ways to Beat Zimmer  
#10

**Zimmer's HXLP Longevity® and Durasul® Polys Are Showing Weaknesses**

- Zimmer's own Ray Crowninshield questions the utility of Highly Crosslinked Poly in certain BIG HEAD applications!

*"Understanding of the utility...of these bearing surfaces and their limitations is renewed importance."*

Reference: HALLEY, D., GLASSMAN, A., CROWNINSHIELD, R.  
"Increased Osteolysis After Revision Total Hip Replacement with a Large Frictional Femoral Head" THE JOURNAL OF BONE & JOINT SURGERY VOLUME 44-A, NUMBER 4

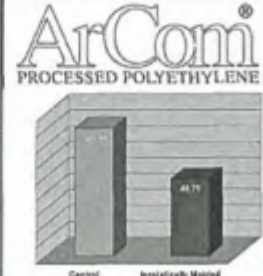

21 Ways to Beat Zimmer  
#10

**Zimmer's HXLP Longevity® and Durasul® Polys Are Showing Weaknesses**

**ArCom<sup>®</sup>**  
PROCESSED POLYETHYLENE

8-Year Clinical F/U  
40 % Wear Reduction  
Zero Osteolysis

*Head, et al. SICOT 2002*

21 Ways to Beat Zimmer  
#10

**ArComXL**  
highly crosslinked polyethylene


- High Strength
- Low Wear
- No Oxidation
- November '04







21 Ways to Beat Zimmer  
**#10**

### The ArComXL Process




ArCom ICM Barstock      50 kGy Gamma Irradiation      Below Melt Pre-Heat      Solid State Deformation




21 Ways to Beat Zimmer  
**#10**

### The ArComXL Process




Low Heat Stress Relief      Machining      Gas Plasma or ETO Sterilization




21 Ways to Beat Zimmer  
**#11**

### Zimmer's Constrained Liners Are **Only 2<sup>nd</sup> Best**




Zimmer Trilogy Constrained Liner

- Zimmer promotes the Trilogy® Constrained insert as having 104 degrees ROM.
- According to the package insert, ROM decreases to less than 90 degrees when used with a 12/14 tapered stem (i.e. Versys®).




21 Ways to Beat Zimmer  
**#11**

### Zimmer's Constrained Liners Are **Only 2<sup>nd</sup> Best**



Zimmer Epsilon Constrained Liner



- Zimmer's other constrained liner, the Centerpulse Epsilon® Constrained Insert seems perfectly engineered for the laboratory setting.
- But 55 degrees Abduction? Higher risk of dislocation
- Crowninshield warns of excessively Abducted cups and their propensity for increased wear and lower resistance to dislocation (Harvard Hip Course Presentation, 2003).



21 Ways to Beat Zimmer  
**#11**

### Zimmer's Constrained Liners Are **Only 2<sup>nd</sup> Best**



- The Freedom has been implanted in over 1,000 cases since its introduction in June of 2003 and continues to be extremely successful.


21 Ways to Beat Zimmer  
**#11**

### Biomet's Constrained Liners **ARE The BEST**

- Freedom® Liners **SELL PRIMARY STEMS**
- Top FIVE Freedom™ Liner distributors booked 50% of ALL SALES during Q1


21 Ways to Beat Zimmer  
**#12**




Zimmer ZMR Hip

**Zimmer's ZMR® Modular Revision Is Weak**

- Zimmer sells more ZMR® Hips than Biomet, yet the Mallory-Head Modular Calcar has very favorable clinical results.
- Voluntary manufacturer recall
- Mechanical testing protocol based on Pre Roller-Hardened technology
- Stem predicate device is actually the M-H Mod Calcar
- Roy Crowninshield published a paper in defense of poor product performance, blaming poor surgeon judgement
- NO clinical history.




21 Ways to Beat Zimmer  
**#12**




Biomet Mallory-Head Modular Calcar

**Zimmer's ZMR® Modular Revision Is Weak**


- **Mallory-Head® Modular Calcar**
  - Well-respected trade name
  - Proven trochanteric re-attachment option
  - Myriad distal options
  - Zero Taper Breakages/5,000+ cases
  - Clinical history!



21 Ways to Beat Zimmer  
**#13**




**Secret to Modular Revision Success: Roller Hardening**



21 Ways to Beat Zimmer  
**#13**

**Secret to Modular Revision Success: Roller Hardening**


- Patented process developed at Biomet.
- Not developed to address weakness in non-roller hardened tapers in previous system.
- Zimmer's "Ti-Nitriding" process only hardens the SURFACE to a depth measured in microns.



21 Ways to Beat Zimmer  
**#13**



**Secret to Modular Revision Success: Roller Hardening**

- 5,000+ implants with no reported fractures at the taper junction.
- 3 published papers documenting the clinical success of the product.



21 Ways to Beat Zimmer  
**#13**

**# Of Clinical Papers for Currently Marketed Zimmer Revision Stems**

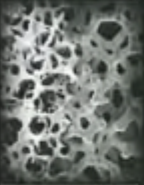






21 Ways to Beat Zimmer  
**#14**

Tantalum Has **NO ADVANTAGE** over Titanium Alloy

- Contrary to popular rhetoric, Tantalum has NOT been shown to be any more conducive to bone formation than the proven Titanium Alloy **all** orthopedic companies use.



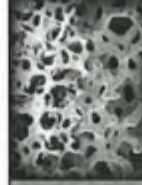
Zimmer Trabecular Metal




21 Ways to Beat Zimmer  
**#14**

Tantalum Has **NO ADVANTAGE** over Titanium Alloy

- Tantalum has never been used before in a load-bearing medical device application.
- High infection rates (up to 17%) in revisions mean that removal of Tantalum implants may be extremely damaging.
- Tantalum's porosity is great...unless the patient needs a revision.
- Allograft bone has been shown to perform well in revision acetabular setting.
- This is a **solution** in search of a **problem**.



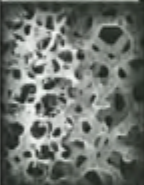
Zimmer Trabecular Metal




21 Ways to Beat Zimmer  
**#14**

Tantalum Has **NO ADVANTAGE** over Titanium Alloy

- Hospitals **continue** to pay top dollar for these clinically irrelevant implants.
- Ways Tantalum is **Better** than Titanium:
  - Biocompatibility? No!
  - Cup Placement? No!
  - Joint Stability? No!
  - Ease of Operation? No!
  - Infection Control? No!
  - Fixation? No!
  - Survivorship?



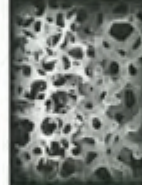
Zimmer Trabecular Metal




21 Ways to Beat Zimmer  
**#14**

Tantalum Has **NO ADVANTAGE** over Titanium Alloy

- Par 5® Cup
- Healey™ Flanged Cup
- McLaughlin™ +5 Shell
- Max-Ti® Protrusio Cage
- Mallory-Head® Protrusio Cage
- Recovery™ Cage
- Biomet Tri-Flange



Zimmer Trabecular Metal



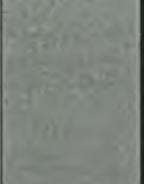
21 Ways to Beat Zimmer  
**#15**

No Clear Benefit to Zimmer's 2-Incision Technique


- Small scars? Yep! But...
  - Requires use of **distally-loading** stem
  - Lack of exposure **limits visualization**
  - Fluoro-Based visualization requires **heavy lead vests** (hot, uncomfortable)
  - Limited "Bail-Out" options
  - Extended Operating Time

With 98% survivorship at 15 yrs, what real Benefit will the patient enjoy?

Dr. Ranawat has questioned the ethical nature of the 2-incision approach.



Zimmer Trabecular Metal

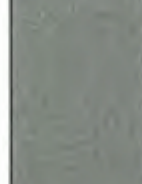


21 Ways to Beat Zimmer  
**#15**


No Clear Benefit to Zimmer's 2-Incision Technique

**Dr. Hartzband:**

- "It took me **100 cases** to get real comfortable."
- "I tell my patients **not to believe the hype**."
- "This procedure is only for surgeons doing 200-240 hips per year, **not for the surgeon doing 30 hips per year**."




Zimmer Trabecular Metal



21 Ways to Beat Zimmer  
**#15**

**No Clear Benefit to Zimmer's 2-Incision Technique**

- What is the long-term efficacy of MIS techniques?
  - Limited number of short-term clinical studies
    - \* List studies!
  - Long-term follow-up not yet possible
  - Debatable short-term benefits
  - No clinical results for Zimmer implants.
- Biomet's Microplasty™ uses clinically proven implants.




21 Ways to Beat Zimmer  
**#16**

**Possibly *MIS*leading Patient Promotions**

- "Q. Is there a difference between the replacement hip used in the *MIS* 2-Incision procedure and the one used in traditional hip replacement surgery?"
- "A. No. The replacement hip – comprised of a stem, ball and socket – is the same high quality, clinically proven prosthesis that is used in traditional surgery."
- **No clinical results on the Versys® Hip**


Reference: Zimmer Holdings, Inc.  
<http://www.zimmer.com/US/Products/Products%20List.htm>  
2010-01-01



21 Ways to Beat Zimmer  
**#16**

**Microplasty™**  
minimally invasive program

- **Microplasty™ Techniques** are developed to be practical and reproducible.
- **Microplasty™ Instruments** allow for gradually working standard techniques down to less invasive techniques.
- **Microplasty™ Training** allows surgeons to gain practical MIH experience without signing an option-limiting contract
- **Rapid Recovery Program™** assists patients while promoting surgeon practices.




21 Ways to Beat Zimmer  
**#16**

**Possibly *MIS*leading Patient Promotions**

"Thousands of *MIS* hip and knee procedures have been performed. **At 6 months, the clinical outcomes are impressive and well documented.** Results indicate that the efficacy of *MIS* procedures parallels those of open procedures.<sup>1</sup>"


1. "Data on File at Zimmer"  
Last Updated 8/19/04

Reference:  
<http://www.zimmer.com/US/Products/Products%20List.htm>




21 Ways to Beat Zimmer  
**#17**

**Possibly *MIS*leading Patient Promotions**




Patients **may** not be told that surgeons using "MIS" instruments **may** be contractually obligated to Zimmer to use their implants for the surgery.




21 Ways to Beat Zimmer  
**#17**

**Possibly *MIS*leading Patient Promotions**

**"Hip Surgery Today, Tennis Tomorrow?"**




- Misleading headlines like this one from NBC Channel 5 in Chicago, are being used to promote the Zimmer MIS technique.
  - This particular article features Zimmer doctor, Mark Hartzband.
- Remember, Dr. Hartzband's comments from earlier:  
*"I tell my patients not to believe the hype."*






21 Ways to Beat Zimmer  
#17

Possibly **MISleading** Patient Promotions




- Few data support Zimmer's MIS approach.
- Several papers have found that a "small incision" offers no benefit! (references here)
- Waldman reports good results with small incisions...but he is using Biomet's clinically proven implants.
- Patients are far more concerned with the first 2 months, not the ensuing 20 years.




21 Ways to Beat Zimmer  
#17

Possibly **MISleading** Patient Promotions




- Dr. Rich Berger claims that "You can do [minimally invasive surgery] with two incisions, three incisions, or ten incisions...as long as you don't cut the muscles or tendons." (Orthopedics, April 2004)
- Also, "two to ten cases" are usually sufficient to become comfortable with the 2-incision technique.
- Put other quote that says it takes a LONG time to get comfortable with min incision.
- But Dr. Hartzband says "this procedure is only for surgeons doing 200-240 hips per year."




21 Ways to Beat Zimmer  
#17

Possibly **MISleading** Patient Promotions




- "Many clinical studies initiated by Zimmer are approved and monitored by hospital Investigational Review Boards."
  - Required by HIPPA!
  - Weak attempt to gain credibility

Reference: Zimmer Holdings, Inc.  
<http://www.zimmer.com/ci/Doc-af/bal/balDoc-100/>  
<http://12318.com/pat-01/>




21 Ways to Beat Zimmer  
#17

Possibly **MISleading** Patient Promotions



"We use a cementless prosthesis that grows into bone, and most leave the hospital on crutches the day of the operation."


– Richard Berger, M.D. in The National Enquirer (Dec. 9, 2003)



21 Ways to Beat Zimmer

Summary Slide" Everything we've talked about


- Point
- Point
- Point
- Point



Magnum™  
large medial articulation

Overshadowing Zimmer:  
Large Articulations

- Jumbo, Hemispherical, One-Piece Cup
- **Huge** ROM and Stability
- Closely Replicates Patients' Natural Head Size
- FDA Clearance: Expected November '04




#18

21 Ways to Beat Zimmer

**More Cutting Edge than Zimmer:**  
Hemi Resurfacing

- Point
- Point
- Point
- Point




#21

21 Ways to Beat Zimmer

**Mention other webcasts against**  
DePuy, S-N, Howmed

- Point
- Point
- Point
- Point



#21

21 Ways to Beat Zimmer

**Thank You**

- 30 minutes for question/answer
  - Ask over the phone via operator
  - Type in questions on your computer

